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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,812	02/25/2002	James W. Simpkins	1540/144	2471

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BROMBERG & SUNSTEIN LLP
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BOSTON, MA 02110-1618

EXAMINER

BETTON, TIMOTHY E

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/082,812

Applicant(s)

SIMPKINS, JAMES W.

Examiner

Timothy E. Betton

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1 sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 20 November 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Instant claims 1 and 4 are pending. Claims 2,3, and 5 are canceled.

Claim Rejections- 35 USC§ 112, 1ST Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1^{and 4} is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Instant claim 1, line 5, cites the term "prophylactic". The instant specification on page 11 cites the only three disclosures containing the term "prophylactic" or "prophylactically", however the specification fails to adequately describe and/or explain the central issue involving prophylactic properties and administration directed to instant

Art Unit: 1614

invention. Thus, prophylactic practice is not supported in the specification. Further, the specification has not predictably enabled a prophylactic amount practice as noted in instant claim 1. Instant claim 4 is dependent from instant claim 1 and is also thereby rejected.

Claim Rejection- 35 USC§ 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simpkins (USPN 5,877, 169), in view of Chopp et al. (USPN 6,245,757 B1).

Simpkins teaches a method of conferring protection on a population of cells associated with an ischemic focus, in subject, comprising:

- (a) providing an estrogen compound having insubstantial sex-related activity; and
- (b) administering an effective cumulative amount of the compound over a course that includes at least one dose within a time that is effectively proximate to the ischemic event, so as to confer protection on the population of cells. Also directed is a method of treating a myocardial infarct in a subject and an ischemic event with the above combination (Abstract; see Figure 1; column 4, lines 1-25, 55-65).

Art Unit: 1614

Chopp et al teach a method for the treatment of ischemic damage, such as damage due to stroke or myocardial infarction, is provided, comprising administering to a mammal afflicted with stroke, an effective amount of a progestin in a suitable vehicle (Abstract; column 7, lines 34-61).

Chopp et al. do not teach an alpha isomer of estrogen.

Simpkins et al. teach an estrogen compound having insubstantial sexual activity.

It would prima facie obvious to one of ordinary skill in the pertinent art to at once recognize the reasonable expectation of success via the combining of the methods of Chopp et al. with the methods of Simpkins et al. For instance, instant claim 1 is drawn to a method for mitigating the effects of a future ischemic event in a subject via identification of a susceptibility profile and the administration of 17-alpha estradiol, an alpha isomer of estrogen. Correspondingly, Simpkins encompasses the subject matter and central issue of instant invention, teaching a similar estrogenic moiety and same disclosed therapeutic indication. Likewise, Chopp et al. teach the administration of progestin as method of preventative treatment for an ischemic event. It would be *prima facie* obvious to interchange progestin for estrogen or vice-versa due to their obvious variance, i.e., same classification, similar susceptibilities, properties, and characteristics directed to treatment for ischemia and associated conditions. The motivation to combine Chopp et al. and Simpkins et al. is disclosed within the central issue of each referenced patent. The combining of the inventions of Chopp et al. and Simpkins et al encompasses the central issue of the claimed invention.

Art Unit: 1614

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ardin H. Marschel 4/2/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

TEB